K113357

MAR 2 1 2012

510(k) Summary for the Posey Bed 8070

SUBMITTER:

J. T. Posey Company
5635 Peck Road
Arcadia, California 91006 USA

CONTACT PERSON:

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DATE PREPARED:

November 9, 2011

DEVICE TRADE NAME:

Posey Bed 8070

COMMON/USUAL NAME:

Enclosed Bed System

CLASSIFICATION NAME:

Protective Restraint (21 CFR §880.6760), Code FMQ

SUBSTANTIAL EQUIVALENCE:

The proposed device, the Posey Bed 8070 with modified labeling to include home use, is the same unchanged device previously cleared by the FDA under K103817 via the 510(k) notification process, and is substantially equivalent for design and materials. This 510(k) establishes that the Posey Bed 8070 is also substantially equivalent to the Soma Safe Enclosure, as used with an AC-powered adjustable hospital bed, for the home use environment, (K963701).

DEVICE DESCRIPTION:

The Posey Bed 8070 is an enclosed bed canopy system which includes and attaches to a fully automatic, AC-powered adjustable hospital bed (either the Joerns Healthcare, Inc., Stevens Point, Wisconsin, Easy Care® 2003DC, Model B684DC or the Invacare Corporation, Elyria, Ohio, Model SC900DLX-POS Low Electric Bed), which has a six-inch enclosed mattress compartment to help reduce the risk of patient entrapment. The device also features a 70 cubic-foot rectangular green nylon canopy with four zippered access panels for easy access to patients and four ports for intravenous lines, call bells and drainage bag openings. The bed has a control that allows the

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frame to be raised to 30 inches for patient care or lowered to 19 inches for ease of wheelchair transfers. A perimeter guard is available as a temporary guard for use when patient care is being given.

The Posey Bed 8070 does not have side rails, headboards or footboards. Contained within the canopy is a specialized compartment for the mattress to prevent the mattress from moving within the canopy and the patient from crawling under the mattress. These features provide a system that minimizes the potential for patient entrapment.

Other safety features include a perimeter guard (reference: Soft Rails) that provides an additional measure to protect the patient from falling when the canopy is opened and a health care provider is attending to the patient.

Optional accessories include filler cushions, torso cushions, bed support surface, incontinence pads, and travel covers.

INTENDED USE:

The Posey Bed 8070 is a hospital bed, canopy, and mattress system designed to help provide a safe, controlled environment for patients at extreme risk of injury from a fall or unassisted bed exit. The Posey Bed 8070 is a less restrictive alternative to physical restraints such as belts, vests, or jackets for patients at least 46 inches tall, weighing between 46 and 300 pounds. The Posey Bed 8070 is a restraint, and must be prescribed by a licensed physician that includes Rx use in the home environment.

TECHNICAL CHARACTERISTICS:

The Posey Bed 8070 is the same product as that previously cleared under K103817, however, it is now being proposed for expanded use in the home environment. A comparison of device features in K103817 demonstrated that the Posey Bed 8070 is substantially equivalent to the currently marketed Soma Safe Enclosure, as used with an AC-powered adjustable hospital bed. Both devices utilize equivalent fabrics, mesh and zippers and are framed, enclosed canopies.

PERFORMANCE TESTING:

Results of biocompatibility (ISO 10993), human factors, and performance testing have established that the Posey Bed 8070 for use in a home care environment is suitable for the intended use indicated and is substantially equivalent to the previously cleared Posey Bed 8070 and the Soma Safe Enclosure.

The human factors testing conducted by caregivers was used to validate the design of a training regimen and Instructions for Use to include safe and effective device interactions in a home environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Bonnie Bishop, RAC
Vice President, Quality Assurance and Regulatory Affairs
J.T. Posey Company
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Arcadia, California 91006

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Re: K113357
Trade/Device Name: Posey Bed 8070 (for home use)
Regulation Number: 21 CFR 880.6760
Regulation Name: Protective Restraint
Regulatory Class: I
Product Code: OYS
Dated: February 22, 2012
Received: February 23, 2012

Dear Ms. Bishop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K113357

Device Name: Posey Bed 8070 (for home use)

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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/21/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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